DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Adminiatration
Rockville MD 20857

SP 98P-1196/CP 1

MAR 26 1999

Robert D. Gunderson
Vice President, Regulatory Affairs
Phoenix Scientific, Inc.
3915 S. 48th St. Terrace
P. O. Box 6457
St. Joseph, MO 64506-0457

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Dear Mr. Gunderson:

We refer to your suitability petition filed December 17, 1998, in which you requested permission to submit an abbreviated new animal drug application (ANADA) to provide for the use of a generic propofol injection. The proposed generic differs in strength and inactive ingredients from the pioneer product, Schering-Plough's (formerly Mallinckrodt Veterinary's) Rapinovet™ (NADA 141 -070). Change in strength is an allowable difference which may be considered in a suitability petition, as provided by the Generic Animal Drug and Patent Term Restoration Act, section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

The proposed generic contains 100-mg/mL propofol for IV use in dogs, whereas the pioneer product contains 10-mg/mL propofol for IV use in dogs – a tenfold difference.
The labeling for the pioneer product states that propofol is intended for induction and maintenance of general anesthesia in dogs with or without other anesthetics. The labeling for the pioneer shows that induction dose ranges are narrow (5.5-7.0 mg/kg body weight) and dosage rates are critically dependant on volume (0.37 – 0.70 mL/kg per minute) for dogs given propofol alone. The labeling cautions that rapid administration or accidental overdosage may cause necrologic and cardiopulmonary depression, and that respiratory arrest may occur. If the product is injected too slowly, an inadequate plane of anesthesia can occur. Therefore, because the strength of the generic would be tenfold that of the pioneer, studies other than bioequivalence will be required to demonstrate the safety and/or effectiveness of propofol injection for induction and maintenance of anesthesia.

Section 510 of the FFDCA provides for suitability petitions to be denied if investigations must be conducted to show the safety and effectiveness, in animals to be treated with the drug, of the strength of the proposed product when it differs from the strength of the approved new animal drug.

Because investigations beyond bioequivalence are required for approval of your proposed product, the suitability petition is denied. Hence, the product is ineligible for consideration under an ANADA. A New Animal Drug Application (NADA) would be required to obtain approval of your proposed product.

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If you disagree with our denial of your suitabil ity petition, you may petition for reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Such a petition must be based solely on the information and views contained in your original petition and must be submitted in accordance with § 10.20 in the format outlined in $10.33. The petition for reconsideration must be submitted no later than 30 days after the date of this denial of the suitability petition, and should be filed with the Dockets Management Branch, Food and Drug Administration, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please refer to the docket number cited above in any submission regarding this original suitability petition.

If there is additional information, not included as part of your original submission, that you would like the agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch, at the address noted above.

We note that there is an unexpired five-year exclusivity period listed in the FDA *Approved Animal Drug Products* for NADA 141-070. Because the listed animal drug product has a five-year exclusivity period, an abbreviated application cannot be submitted before November 6,2001:

141-070 Rapinovet™ 5 years, Expiration Date, Nov 6, 2001; Green Book Supplement, Jan-1997

If you have additional questions about the specific requirements for the NADA, please contact Dr. Melanie Berson, Director, Division of Therapeutic Drugs for Non-Food Animals (HFV-1 10), telephone (301) 827-7543.

Sincerely yours,

Margaret Ann Miller

Margaret Ann Miller, Ph.D.
Acting Director, Office of New
Animal Drug Evaluation
Center for Veterinary Medicine

MEMO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

DATE: March 26, 1999

FROM: Animal Scientist
Quality Assurance Support Staff, HFV-102

SUBJECT: Suitability Petition Response for Display.

TO: Lyle Jaffe, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD
Dockets Management Branch

The attachment is the Center for Veterinary Medicine's response to Suitability Petition **SP 98P-1196CP 1,** filed as a Suitability Petition on 12/1 7/98. We are forwarding a copy of the signed response for public display with the petition.

A copy of the DMB cover sheet is also attached.

The Center's letter in response to Phoenix Scientific is dated March 26, 1999.

If you have any questions, please callmeat827-0211, or FAX 594-2297.

Thank yOU.

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Sam Hansard, Ph.D.

Attachment

Samuel Hansard, Ph.D.
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